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PAPER NO. 15

[Lipovsky Art Unit 125
700,165 02/11/85]
Charles E. Clum et al]

• SKIN CARE COMPOSITIONS

Before the Board of Appeals

Leonard P. Prusak
For Appellants

Examiner's Answer

MAILED

MAR 02 1987

GROUP 12

BOARD OF PATENT APPEALS
AND INTERFERENCES

87-2039

This is an appeal from the final rejection of claims 1 and 4-6. No claims are allowable. No amendments after final were filed. A correct copy of the appealed claims appears on pages 2 and 3 of appellants' brief. The Declaration of Semple filed September 2, 1986 has been considered but is not seen to substantiate synergism for the scope of claimed compositional ratios.

Serial No. 700,165

-2-

Art Unit 125

THE REFERENCE OF RECORD RELIED ON IS:

4,318,926 Schmidt-Ruppin et al 3/82

The claimed invention relates to compositions of miconazole nitrate and zinc oxide and methods of using such to treat diaper rash.

THE REJECTION

Claims 1 and 4-6 stand rejected under 35 U.S.C. 103 as being obvious over Schmidt-Ruppin et al. who teach the use of topical creams and ointments containing zinc oxide (column 8; lines 30-34) which may additionally contain biologically active substances including miconazole (column 8, line 67- column 9, lines 15). The determination of both optimal proportions and target use are deemed as being matters of obvious alternative to one with skill in the art. Applicants' showings are noted, but are not deemed to be persuasive since the proportional ratios exhibiting synergism are not commensurate with the scope of the claims.

RESPONSE TO APPELLANTS' ARGUMENTS

Appellants' arguments regarding their substantiation for the claim of synergism for the combination of miconazole nitrate and zinc oxide at a proportional ratio of 1:60 have been considered but are not seen as persuasive. Despite appellants' contentions, the data present in the specification and the Declarations do not support the claim of synergism within the lower range of

Serial No. 700,165

-3-

Art Unit 125

the presently claimed compositional ratios. Tables I-IV of the specification substantiate synergism for the minimal proportions of 1:110, 1:84, 1:239 and 1:120 respectively. Appellants' contention that Table II substantiates synergism for the proportion of 1:42 is not held by the examiner as the difference between 39.6 and 35.2% inhibition is considered minimal ($\approx 10\%$) and not seen to be of a degree which definitively reflects synergism. Three subsequent declarations were filed. An initial declaration of Semple, filed April 8, 1986 was not found to be persuasive as it failed to present the data from which its conclusions were based. A declaration of Isaacson, filed April 8, 1986 was persuasive in substantiating synergism of a 1:60 mixture of miconazole nitrate and zinc oxide against one organism; Straphylcoccus aureus. A second declaration of Semple, filed September 4, 1986, presented data regarding a 1:60 mixture of miconazole nitrate and zinc oxide vs. Casndida Albicans. It is the Examiner's position that the shown enhancement of microbial inhibition ($\approx 8-25\%$) is considered minimal and not seen to be of a degree which definitively reflects synergism, particularly when viewed in conjunction with the data of Table III (page 14 of spec.) where appellant can substantiate synergism for a compositional ratio no lower than 1:240.

Serial No. 700,165

-4-

Art Unit 125

In summary, it is the examiners position that the presented data fails to adequately support the allegation of synergism for the claimed range of compositional proportions. For the reasons set forth above, the rejection of claims 1 and 4-6 is seen as sound and should be maintained.

Respectfully submitted,

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A/C 703

557-9590

2/17/87

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